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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/005,184 | 12/05/2001 | Rodney W. Salo | 279.365US1 | 6930 |

21186 7590 02/17/2005

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EXAMINER

MANUEL, GEORGE C

ART UNIT PAPER NUMBER

3762

DATE MAILED: 02/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/005,184 | Applicant(s) SALO, RODNEY W. | |
| | Examiner George Manuel | Art Unit 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/7/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 12 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kramer et al '506.

Kramer et al teach pre-exciting one site relative to another site to alter regional workload and metabolic energy demand in order to allow regions of damaged heart tissue to recover from injury or disease. See col. 6, lines 50-64. The examiner is interpreting an ischemic region to comprise tissue recoverable. Ischemic tissue comprises oxygen deprived tissue which recovers upon receiving adequate oxygen.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

Claims 1- 6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skubitz et al '226 in view of Kramer et al '506.

Skubitz et al teach using a temporary transvenous pacing lead for treating a heart that has been infarcted.

Kramer et al teach pre-exciting one site relative to another site to alter regional workload and metabolic energy demand in order to allow regions of damaged heart tissue to recover from injury or disease.

One of ordinary skill in the art would have found it obvious to use combine the teachings of Kramer and Skubitz et al to deliver pacing pulses in a manner that pre-excites the site or sites in proximity to an infarcted area because this area represents a region of damaged heart tissue.

Regarding claims 3, 4, and 10, pacing modalities comprising inhibited demand ventricular pacing, atrial tracking, and sensing acoustic energy are well known and would have been obvious modifications to include with the pacing system of Skubitz et al in view of Kramer et al.

Claims 7, 8 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skubitz et al '226 in view of Kramer et al '506 and further in view of Adinolfi '842.

Skubitz et al in view of Kramer et al meet all of the claimed limitations except for a patch electrode.

Adinolfi teach using a patch electrode with a pacing system. The system includes a patch electrode 1 having a motion sensor 5 embedded therein electrically connected to components in an implantable housing 41, and a conventional pacing lead 38, also electrically connected to components in the housing 41.

One of ordinary skill in the art would have found it obvious to use a patch electrode as taught in Adinolfi for an electrode in a pacing system of the type disclosed in Skubitz et al in view of Kramer et al because infarcted tissue usually encompasses a region and a patch electrode is an obvious choice of an electrode to cover a region of tissue.

Regarding claim 16, one of ordinary skill in the art would have found it obvious to modify the device to deliver an agent selected from the group consisting of an ACE inhibitor, a beta blocker, a growth factor, and an anti-apoptotic factor because these drugs are well known to be used in patients who have suffered a heart attack and have infarcted heart tissue as a result.

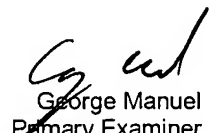
Regarding claim 18, pacing comprising sensing acoustic energy is well known and would have been an obvious modification to include with the pacing system of Skubitz et al in view of Kramer et al and further in view of Adinolfi.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer et al '506.

Pacing modalities comprising impedance sensing and sensing acoustic energy are well known and would have been obvious modifications to include with the pacing system of Kramer et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.


George Manuel
Primary Examiner
Art Unit: 3762

2/15/05